

### **DETAILED ACTION**

The Amendment filed December 21, 2011 in response to the Office Action of June 21, 2011 is acknowledged and has been entered. Claims 21, 24, 25 and 33 have been amended. Claims 21-23, 34-49 are withdrawn. Claims 24-27, and 30-33 are under examination in this Office action.

#### ***Claim Rejections - 35 USC § 112***

Rejection of Claims 24-27, and 30-32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn** in view of Applicant's amendment.

Rejection of Claims 25, 27 and 31-32 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of Applicant's declaration filed on 12/21/2011.

#### ***Specification***

Applicant amended the specification to recite "A sample of recombinant adenovirus RAdES was deposited with ECACC under Accession Number 04121701". This amendment to the specification does not sufficiently comply with CFR 1.809 d) which requires the following:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
  - (1) The accession number for the deposit;
  - (2) The date of the deposit; (missing)
  - (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

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- (4) The name and address of the depository. (missing)

***Oath/Declaration***

Applicant must file new Oath or Declaration under 37 CFR 1.67 referring to the preliminary amendment filed on June 11, 2008 reciting the EACC Accession Number 04121701 because this particular limitation was not present in the originally filed claims, specification or drawings filed on June 29, 2006, see MPEP 608.04(b).

**608.04(b) [R-3] New Matter by Preliminary Amendment**

**\*\*>** A preliminary amendment present on the filing date of the application (e.g., filed along with the filing of the application) is considered a part of the original disclosure. See MPEP § 714.01(e) and § 602. A preliminary amendment filed after the filing date of the application is not part of the original disclosure of the application. See MPEP § 706.03(o). For applications filed on or after September 21, 2004, the Office will automatically treat any preliminary amendment under 37 CFR 1.115(a)(1) that is present on the filing date of the application as part of the original disclosure. If a preliminary amendment is present on the filing date of an application, and the oath or declaration under 37 CFR 1.63 does not also refer to the preliminary amendment, the normal operating procedure is to not screen the preliminary amendment to determine whether it contains subject matter not otherwise included in the specification or drawings of the application as filed (i.e., subject matter that is “new matter” relative to the specification and drawings of the application). As a result, it is applicant’s obligation to review the preliminary amendment to ensure that it does not contain subject matter not otherwise included in the specification or drawings of the application as filed. If the preliminary amendment contains subject matter not otherwise included in the specification and drawings of the application, applicant must provide a supplemental oath or declaration under 37 CFR 1.67 referring to such preliminary amendment. The failure to submit a supplemental oath or declaration under 37 CFR 1.67 referring to a preliminary amendment that contains subject matter not otherwise included in the specification or drawings of the application as filed removes safeguards that are implied in the oath or declaration requirements that the inventor review and understand the contents of the application, and acknowledge the duty to disclose to the Office all information known to be material to patentability as defined in 37 CFR 1.56.

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***New Claim objection necessitated by Applicant's amendment***

***Claim Objections***

Claims 24-27 and 30-33 are objected to because of the following informalities:

Claim 25 recites:

25. (Currently Amended) A recombinant adenovirus RAdEs immunogenic composition a representative sample of RAdEs has been deposited under ECACC Accession Number 04121701, said composition comprising JEV Es protein optionally with pharmaceutically acceptable additives.

It is not clear whether the claimed composition comprises just the RAdEs plasmid? Does the plasmid comprise the JEV protein? Or the composition specifically comprises the construct deposited under ECACC Accession Number 04121701?

Applicant is suggested to amend the claim to recite:

“A recombinant adenovirus immunogenic composition comprising RAdEs plasmid encoding the Japanese encephalitis virus (JEV) secretory envelope protein (Es), said recombinant adenovirus deposited under under ECACC Accession Number 04121701, optionally with a pharmaceutically acceptable additives.”

Applicant is suggested to amend claim 24 to specifically indicate the components of the recombinant adenovirus RAdEs immunogenic composition, for example:

“A recombinant adenovirus immunogenic composition comprising RAdEs plasmid encoding the Japanese encephalitis virus (JEV) secretory envelope protein (Es) prepared by the method comprising the steps of: (...).”

Appropriate correction is required.

***Conclusion***

Applicant's amendment necessitated the new ground of rejections presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/  
Primary Examiner, Art Unit 1648